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10/684,473	10/15/2003	Kazunori Okano	HIRA.0124	5218

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EXAMINER
BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/684,473	**Applicant(s)** OKANO ET AL.	
	Examiner Nathan A. Bowers	**Art Unit** 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-15 and 19* is/are rejected.

7)☒ Claim(s) *16 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-4, 10-12, 13-15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardell (US 20020015959) in view of Stocker (US 4339241).

With respect to claims 1-4, 13, 19 and 20, Bardell discloses a solution mixing apparatus and method comprising a holding plate (Figure 5:40) for holding at least one substrate (Figure 5:30) on which at least one probe (Figure 5:34) is immobilized. A moving plate (Figure 5:38) is placed close to the substrate with a gap therein so as to accommodate a solution containing at least one substance therebetween. The moving plate moves relatively to the holding plate to mix the probe with the solution. According to paragraphs [0024]-[0028], the moving plate is capable of oscillating back and forth across the slide (moving across the holding plate in one direction forwards and backwards), as well as revolving relatively to the holding plate in the direction shown by arrow B. Paragraph [0003] indicates that biochemical reactions are facilitated using the disclosed invention, and paragraphs [0010] and [0012] teach that the biochemical reactions involve immobilized probes. It is an inherent property of the disclosed invention that shapes of the moving plate and probe area are conducive to promoting uniform mixing and providing an equal solution flow volume at each location on the probe area. Bardell, however, does not expressly disclose that the moving plate is hydrophilic on the surface.

Stocker discloses a solution mixing apparatus for providing reactions therein comprising a substrate (Figure 5:20), as well as a cover plate (Figure 5:28) that is positioned close to the substrate with a gap therein so as to accommodate a solution containing at least one substance therebetween. The substrate is coated with a hydrophobic substance except for specified areas (Figure 3:24) where the reaction fluid is allowed to accumulate. Stocker indicates that surfaces of the substrate and cover plate that are positioned below and above these areas are not hydrophobic. Since these surfaces are not hydrophobic, they are considered to be hydrophilic. The substrate and cover plate are moved relative to one another using a spring (Figure 5:8) in order to induce mixing. All of this is disclosed in column 2, line 51 to column 3, line 24 and in column 4, lines 31-52.

Bardell and Stocker are analogous art because they are from the same field of endeavor regarding mixing apparatuses for biochemical reactions.

At the time of the invention, it would have been obvious to ensure that the moving plate in the invention disclosed by Bardell was comprised of a hydrophilic surface. Stocker teaches in column 2, line 51 to column 3, line 24 that hydrophilic surfaces are more useful than hydrophobic surfaces because hydrophilic materials allow a solution sample to easily flow within the reaction space. Hydrophobic surfaces cannot effectively interact with a sample solution, and therefore cannot mix a fluid as readily as hydrophilic materials that are capable of developing stronger adhesive forces with the fluid. Accordingly, hydrophobic surfaces are known in the art to restrict liquid movement over a surface. Since it is critical that the solution volume flows evenly and unhindered in Bardell's device, it would have been obvious to make the moving plate hydrophilic on its surface in order to promote effective mixing.

With respect to claims 12 and 15, Bardell and Stocker disclose the apparatus in claims 1 and 3. In addition, Bardell indicates that the moving plate and the area where the probe is immobilized are circular. This is disclosed in Figures 2-4. From the Figures, it is clear that the diameter of the moving plate is equal to the diameter of the probe immobilized area.

With respect to claims 10 and 11, Bardell and Stocker disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although Bardell does not expressly disclose a specific rate at which the moving plate rotates, it would have been obvious to design the motion of the moving plate to accordingly meet the claimed limitations. Varying the velocity at which the moving plate moves to achieve favorable mixing is simply the optimization of result effective variables that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the moving plate moved at a velocity of 0.9-30 seconds per one moving cycle. This would guarantee efficient mixing, which in turn would increase the diffusion rate of particles in solution and decrease the time required for the reaction to take place. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claim 14, Bardell and Stocker disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. Bardell discloses an embodiment represented in Figure 5 wherein the revolving plate (Figure 5:38) is circular and the probe-immobilized area (Figure 5:34) is polygonal. Bardell discloses another embodiment represented in Figures 2-4 wherein the revolving plate (Figure 3:26) is circular and has a diameter that is equal to the diagonal length of the probe-immobilized area (Figure 2:22). Yet, Bardell does not disclose a single embodiment that includes a circular revolving plate whose diameter is equal to the diagonal length of a polygonal probe-immobilized area. However, in the absence of new or unexpected results, it would have been obvious to combine the two disclosed embodiments to develop a solution mixing apparatus comprising a circular moving plate and a polygonal probe-immobilized area that are similarly sized, if such an arrangement promoted efficient mixing. Varying the geometry and sizes of the moving plate and probe area to achieve the most favorable design is simply the optimization of result effective variables that could be pursued using routine experimentation. The manipulation of the geometry and sizes of the moving plate and probe area would have been beneficial because it would have helped promote efficient and uniform mixing. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardell (US 20020015959) and Stocker (US 4339241) as applied to claim 1, and further in view of Palander (WO 9621142).

Bardell and Stocker disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the gap between the moving plate and the substrate ranges from 50,000 to 100,000 nm.

Palander discloses an apparatus for mixing a solution comprising a substrate and a moving plate that together define a gap within which the solution resides. This is disclosed on page 5, lines 1-25 and in Figure 1. Additionally, Palander teaches that the gap distance between the substrate and moving plate is between 20 micrometers and 300 micrometers.

Bardell, Stocker and Palander are analogous art because they are from the same field of endeavor regarding the use of movable plates to induce mixing in a biochemical reaction apparatus through the transfer of momentum.

At the time of the invention, it would have been obvious to utilize the gap distances disclosed by Palander in the overall apparatus disclosed by Bardell and Stocker. Micrometer and nanometer sized gaps allow the moving plate to efficiently mix the entire solution volume, since fluids are more effected by the motion of the moving plate when their proximity to the moving plate is decreased. The gap distance proposed by Palander is beneficial because diffusion of analytes in solution, and subsequent reaction with the immobilized probes, is accelerated when the moving plate mixer is brought closer to the substrate.

3) Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardell (US 20020015959) and Stocker (US 4339241) as applied to claim 1, and further in view of Takagi (US 20040235150).

With respect to claim 7, Bardell and Stocker disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the apparatus is equipped with a temperature control apparatus.

Takagi discloses a solution mixing apparatus for providing reactions therein comprising a holding plate (Figure 11:4) for holding at least one substrate (Figure 11:10), and a moving plate (Figure 11:24) with one surface being placed close to the substrate with a gap therein. This is disclosed in paragraphs [0036] to [0040]. Takagi teaches in paragraphs [0044] and [0045] that the apparatus is equipped with a temperature control system comprising a temperature sensor (Figure 6:108) and a heating unit (Figure 6:102).

Bardell, Stocker and Takagi are analogous art because they are from the same field of endeavor regarding mixing apparatuses for biological reactors involving moving plates.

At the time of the invention, it would have been obvious to equip the mixing apparatus proposed by Bardell and Stocker with a temperature control system. Bardell teaches in paragraph [0024] that it is common practice to use temperature control systems (heat cyclers) when conducting hybridization reactions since many biological probes and analytes are sensitive to temperature. The inclusion of a temperature control system in Bardell's invention would have been beneficial since it would have been able to provide optimum experimental conditions for most hybridization reactions involving biological compounds.

With respect to claims 8 and 9, Bardell and Stocker disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Bardell teaches in paragraphs [0025] and [0026] that a channel (Figure 3:28) connecting through the moving plate to a space between the substrate and the moving plate is provided for the addition of a solution. Bardell and Stocker, however, do not expressly disclose the use of a solution injection to accomplish this task. Bardell and Stocker do not disclose that a solution injector is also used to inject from the edge of the device a solution between the substrate and moving plate.

Takagi discloses inlet and outlet ports (Figure 1:12 and Figure 1:14) for adding and removing fluids from the side of the mixing device between the holding plate and the moving plate. The addition of solution through the inlet port is achieved in a controllable manner.

At the time of the invention, it would have been obvious to utilize a solution fluid injector to add solutions to the mixing device disclosed by Bardell and Stocker either through the sides or via a channel connecting through the moving plate. The use of fluid injectors would allow one to precisely administer solutions to the apparatus in a way that is not heavily time or labor dependent. Fluid injectors working from the side or through the top of the mixing apparatus could effectively deliver solution either before or during mixing operations.

Response to Amendment

Amendments to claims 1 and 19 filed 22 May 2006 do not reflect changes to the claims initiated by the amendment filed 31 March 2006. It is understood that seeks to cancel the term "in a direction parallel to the holding plate" and replace it with "in a plane thereof."

Response to Arguments

The previously made formal objections and rejections under 35 U.S.C. 112 have been addressed by Applicant, and are therefore withdrawn.

Applicant's arguments, see page 11, filed 06 April 2006, with respect to the rejection of claims 19 and 20 involving Palander have been fully considered and are persuasive. The 35 U.S.C. 103 rejection of these claims has been withdrawn.

Applicant's arguments, see pages 6 and 7, filed 06 April 2006, with respect to the rejection(s) of claim(s) 1 and 6 under 35 U.S.C. 102 (anticipation by Bardell) and 35 U.S.C. 103 (Bardell in view of Oberhardt) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bardell and Stocker.

As indicated in the rejection under 35 U.S.C. 103 above, Bardell does indicate in paragraphs [0010] and [0012] that a probe is immobilized on the substrate. The deficiencies of Bardell are addressed by Stocker, who discloses moving plates with hydrophilic surfaces that interact with a reaction medium.

Applicant's arguments filed 06 April 2006 have been fully considered but they are not persuasive.

With respect to the rejection of claim 5, Applicant's principle arguments are

(a) Palander is not purported to mix a solution effectively. Palander is simply directed to an apparatus for spreading a liquid on a flat surface, and therefore, there is no motivation to combine with Bardell.

In response to Applicant's arguments, please consider the following comments.

It is the Examiner's position that Palander and Bardell are very similar apparatuses. Both involve the treatment of biological samples, and both utilize a cover plate that is movable over a fluid reaction area. Both utilize a moving plate and a holding plate that are adjacent and in close proximity to one another. Although Palander does not specifically disclose that the moving plate produces mixing in the reaction liquid when the moving plate is moved across the substrate, it is the Examiner's position that mixing inherently must occur, especially since Palander's structure and method are, in the most fundamental sense, very similar to those proposed by Bardell and Applicant. It would have been obvious to ensure that Bardell's gap distance is the same as that proposed by Palander since because diffusion of analytes in solution, and subsequent reaction with the immobilized probes, is accelerated when the moving plate mixer is brought closer to the substrate.

With respect to the rejection of claims 7-9, Applicant's principle arguments are

(a) Takagi is directed to an apparatus for cultivating a cell or tissue. Takagi's apparatus is not purported to mix a solution and therefore there is no suggest to combine with Bardell.

In response to Applicant's arguments, please consider the following comments.

Takagi does disclose that the apparatus is used to mix a solution throughout the reference. Notably in paragraph [0008], Takagi states that "the rotation of the disc produces rotating flow in the culture fluid inside the chamber." Since the fluid is being affected in this way by the moving plate, it is the Examiner's position that mixing must be occurring. Since Takagi and Bardell both employ the same basic structure (a holding plate, a moving plate, and reaction fluid in a gap therebetween), it would have been obvious to combine Takagi with Bardell.

Allowable Subject Matter

Claims 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Steinberg (US 20020093878) reference represents the closest prior art in that it depicts a mixing apparatus comprising upper and lower concentric plates (Figure 1:2a and 2b). Paragraphs [0038] teaches that the upper plate is connected to and rotated by a shaft (Figure 1:4). Steinberg, however, does not disclose a moving means which includes a base plate and at least one auxiliary plate, wherein the base plate has the moving plate fixed on one side and the auxiliary plate is rotatably attached on another side.

Conclusion

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAB

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER